UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT UNITED STATES PATENT AND TRADEMARK OFFIC WASHINGTON, D.C. 20231

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

FEB 19 2003 #16

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. Re. 37,721. The application was filed on December 17, 2002, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter

Senior Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner

for Patent Examination Policy

cc:

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RE: ZETIA® (ezetimibe) Docket No. 03E-0035